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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/186,771	11/05/98	HORWITZ	D A-67279/RFT/

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EXAMINER

COE, S

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

08/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/186,771

Applicant(s)
Horwitz

Examiner
Susan Coe

Group Art Unit
1651



☒ Responsive to communication(s) filed on May 22, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11, 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-13 is/are pending in the application.

Of the above, claim(s) 1 and 7-13 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 2-6 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6 and 7

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. Claims 1-13 are currently pending.

Election/Restriction

2. Applicant's election without traverse of Group II, claims 2-6, in Paper No. 10, dated May 22, 2000, is acknowledged.

Claims 1 and 7-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected groups of invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.

3. Claims 2-6 are examined on the merits.

Claim Objections

4. Claim 2 is objected to because of the following informalities: "peripheral" is a misspelling. Appropriate correction is required.
5. Claims 3-5 are objected to as being dependent on nonelected claim 1. Appropriate correction is required.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of systemic lupus erythematosus (SLE), does not reasonably provide enablement for all types of autoimmune diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The specification teaches using inhibitory compositions for treatment of patients with SLE; however, the specification does not teach using the inhibitory composition to treat any other type of autoimmune disorder. The specific immune dysfunction associated with a particular autoimmune disease varies widely based on the disease. A person of ordinary skill in the art would not reasonably expect that a treatment for SLE would also work against other types of immune disorders, such as HIV. Therefore, it would require undue experimentation for an artisan of ordinary skill to determine which autoimmune diseases could or could not be treated

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with the present invention. Thus, from the teaching of the specification, a person of ordinary skill in the art would be able to treat SLE but could not easily determine other types of autoimmune disorders to treat.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2-6 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 is rendered indefinite because the abbreviation "Ig" is not defined in the specification or the claims. While it is noted that "Ig" is commonly known to be the abbreviation for "immunoglobulin," applicant needs to clarify, for the record, what term they consider to be represented by "Ig."

8. No claims are allowed. However, the claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 7:30 to 5:00 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SDC
August 4, 2000



FRANCISCO PRATS
PRIMARY EXAMINER